Kentucky Hospital Association

June 24, 2015

Tricia Orme
Office of Legal Services
275 East Main Street 5 WB
Frankfort, Kentucky 40601

Dear Ms. Orme:

The Kentucky Hospital Association, representing all Kentucky hospitals, appreciates the opportunity to submit comments on the proposed changes to the State Health Plan. The KHA and our member hospitals and systems strongly support having a robust Certificate of Need program in our collective desire to assure access to quality health care services and to uphold the statutory intent of the Kentucky CON program – "to insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth."

The following comments and recommendations have been developed with input from the KHA membership and the KHA Certificate of Need Committee along with approval from the KHA Board of Trustees. We look forward to having the opportunity to meet with the Cabinet in person to answer any questions that may arise from the comments.

Sincerely,

Michael T. Rust

Michael T. Rust
President

Kentucky Hospital Association
State Health Plan Comments
June, 2015

KHA Position on the State Health Plan

Although, KHA had the opportunity to participate in the CON Modernization Comment period, the Cabinet did not afford the opportunity with KHA or its membership in advance of publication to react to the Cabinet's specific proposal included in this plan. There has been no explanation as to the reasoning, need warranting these changes or intended outcome of the proposed changes to the SHP. Additionally, we would like to know what modeling or analysis of the potential impact of these proposed changes would have on existing providers and access to care. We believe it is essential for the Cabinet to withdraw this proposal until the Cabinet has met with providers and industry leaders as well as analyzed and modeled the potential outcomes of these proposed changes. KHA and our members have grave concerns that the majority of the proposed changes have not been fully vetted and could result in significant hardship to existing providers in Kentucky and could actually counter the goal to improve access and quality care. Such sweeping changes should not be done quickly and without serious contemplation, input and collaboration with the industry that is effected by the rule.

KHA produced a white paper, "Certificate of Need: Stabilizing Force for Health Care Transformation" and submitted that document to the Cabinet during the CON Modernization comment period. The core principles, which align with the Cabinet's modernization objectives, highlighted in that paper continue to be the guiding tenet for KHA and our member hospitals and health systems. In summary, the white paper outlines the following:

- Principle 1: Supporting the Evolution of Care Delivery – The evolution in health care delivery that is at the heart of Health Care Reform is not frustrated by CON regulation or the existing criteria in the State Health Plan (SHP). The driving force for new models of care is altering payment incentives, which are independent of CON regulations. However, CON is a stabilizing force which allows existing providers to embrace new payment models, like accountable care organizations and payment bundling, which require a level of risk to be taken by providers. CON as proposed by the Cabinet deregulation under current payment conditions would result in greater fragmentation rather than enhancing the integration of care.

- Principle 2: Incentivizing Development of a Full Continuum of Care – The development of a full continuum of care is precisely the objective of new delivery models that are evolving. The creation of such delivery systems does not require major changes to Kentucky's CON regulations or SHP criteria. In most parts of Kentucky today, there is sufficient availability and capacity of health services to allow new models of care to be developed without allowing unchecked proliferation of new services and facilities. The focus of health care transformation centers on improving population health. Primary care and prevention services for the most part are not covered by the CON program in Kentucky.

- Principle 3: Incentivizing Quality – Quality of care will be a function of the care management systems implemented by organizations. CON deregulation would likely have the effect of diminishing quality of care by reducing volumes across all providers and stretching scarce resources over a greater

number of providers. CON standards in the SHP currently support quality as CON criteria seek to ensure that new facilities operate at volumes that are sufficient to provide quality services as well as assuring that new volume does not come at the expense of existing providers where the lowering of their volumes could reduce quality of existing programs.

- Principle 4: Improving Access to Care – CON deregulation could have the effect of reducing access to care by destabilizing local health care systems. Smaller, rural hospitals and safety-net hospitals in particular are vulnerable to the loss of profitable patients to private organizations that would be developed without CON standards in place. Additionally, new providers likely to enter the market if CON is repealed or weakened would probably target serving patients with commercial insurance which would have an adverse impact on improving access for Medicaid or indigent patients.

- Principle 5: Improving Value of Care - There is no evidence that states without CON programs offer higher value care. To the contrary, in most cases, states without CON have significantly greater duplication of resources and operate on average at lower volumes per provider.

- Principle 6: Promoting Adoption of Efficient Technology – There is simply no relationship between the adoption of efficient technology and CON regulation. Administrative and clinical information systems are not subject to specific CON regulations in Kentucky. With the exception of a few high dollar types of equipment, hospitals and other providers are able to acquire new equipment and technology without facing impediments from the CON program.

- Principle 7: Exempting Services for Which CON is No Longer Necessary – There are no services that the Deloitte Report recommended for elimination of CON review that would appropriately be deregulated. The concern with ensuring sufficient capacity in the future to accommodate a growing base of insured Kentuckians is not based on objective analysis. There are no capacity issues or other considerations that would require the elimination or deregulation of CON to ensure adequate availability of care. The impact on rural hospitals and safety-net hospitals must also be considered when exempting services from review, and such changes could challenge the ability of these providers to offer the same level of access in the future. It is premature today to make changes that will result in greater fragmentation rather than integration of providers. The CON program should be continually reviewed, as it has been, and revised in accordance with health planning principles which consider actual changes in the delivery system and data documenting needs and gaps in services.

Supporting Rural Providers

We understand it is the Cabinet's intent to implement changes to the State Health Plan (SHP) which would be advantageous to rural providers aiming to improve access to quality health care services and support services which improve population health. The Cabinet is aware of a recent study released by State Auditor Adam Edelen which illustrates the ongoing challenges many Kentucky rural hospitals face in maintaining access to essential services and achieving a level of profitability. In the last year, two Kentucky hospitals have closed and an additional hospital has filed for bankruptcy. The challenges rural hospitals face are real and they impact the communities and the health of the populations they serve. We are quite disappointed that the proposed changes to the SHP fall short of protecting existing rural

providers from the unnecessary proliferation of costly health care services. To the contrary, the proposed plan would remove the few services – imaging and outpatient surgery – which are profitable and allow the hospital to maintain access to an emergency department and other essential services to their community. The plan also forecloses the opportunity for some rural hospitals to expand access to services by eliminating the angioplasty program and restricting home health.

There is also a missed opportunity to create a pathway for some small rural hospitals to seamlessly convert to appropriately sized and financially feasible outpatient centers which better meet the needs of the populations they serve. Reports nationally and observations within our own state demonstrate the distinct value that rural hospitals provide to both the physical health of their patients but also the economic health of the communities. We implore the Cabinet to review these proposals and ask the question, *how does this proposal support access to care in rural Kentucky.* We believe the proposal has the potential to further exacerbate the problems many small rural hospitals face and if more hospitals close, the result is the displacement of rural Kentuckians from their homes and local support systems to access health care.

Use of Quality Metrics

KHA applauds the Cabinet for proposing new quality criteria within the State Health Plan as a condition of application. This strongly reflects the statutory intent for the Certificate of Need program. Additionally, we concur with the Cabinet that quality data utilized should be consistent with measures that have been vetted by national organizations like the National Quality Forum and the Centers for Medicare and Medicaid Services (CMS). ***KHA believes that measures must be evaluated for both accuracy and appropriately linked or complimentary to the specific services in question within the SHP for it to be included within the criteria.***

KHA, however, opposes the use of the CMS readmission measure and data for determining eligibility of hospitals to apply for services. There have been numerous national reports and studies which have found that the CMS Hospital Readmissions Reduction Program unfairly penalizes hospitals that provide care for communities with poor socioeconomic indicators. Specifically, the readmission measure does not appropriately adjust for the socioeconomic factor which greatly influences post acute outcomes and the ability and likelihood that patients follow their discharge plan, in spite of the hospitals efforts to best manage the patient after they have been discharged. A sample of these reports follow:

- **A 2013 MedPAC Report**: http://www.medpac.gov/documents/reports/jun13_entirereport.pdf The Medicare Payment Advisory is a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program. Their 2013 report highlighted the importance of risk adjustments and recommended the readmission measure should be improved by evaluating hospital readmission rates against a group of peers with a similar share of poor Medicare beneficiaries and to adjust accordingly.
- **Kaiser Health News report**: http://www.kaiserhealthnews.org/Stories/2012/August/13/hospitals-treating-poor-hardest-hit-readmissions-penalties.aspx. Analysis by Kaiser Health News showed that the Readmissions Penalty program penalizes most hospitals that treat larger populations of low-

income patients when these same hospitals need more resources in place to help patients when they leave hospitals.

- **Health Affairs**: http://content.healthaffairs.org/content/33/8/1314.abstract.
  A report by Health Affairs in August 2014 addressed the concern for Safety-Net Hospitals which treat more low-income patients and the unfair penalties for these facilities.

Additionally, legislation has been introduced at the federal level to address these concerns. *Establishing Beneficiary Equity in the Hospital Readmission Program Act* would adjust the Hospital Readmissions Reduction Program to account for certain socioeconomic and health factors that can increase the risk of a patient's readmission, such as being dually eligible under Medicaid and Medicare.

It is important to note, that in our member hospitals and systems' work towards transitioning their healthcare delivery models and improving outcomes and overall health, hospitals must be able to offer services that supports their work to improve long-term outcomes for their patients. The proposal to use the Readmission Measure particularly within the State Health Plan is counter to that effort. Moreover, post acute services, like home health, may be one of the more valuable tools for hospitals serving comparingly low economic populations to effect improvement on long term outcomes.

We would like to reiterate that reducing readmissions is currently the highest quality improvement focus of our hospitals collectively, according to a recent survey we conducted of our members. They have participated in a great deal of education and training around best practices for discharge planning and working with community partners and physicians. Reducing preventable readmissions is a shared goal for all in healthcare. All Kentucky acute care hospitals are involved in benchmarking readmission data and implementing strategies and resources to actively reduce the readmission rate. KHA welcomes the opportunity to discuss these strategies and activities further. However, our membership is opposed to incorporating a known flawed readmission measure within the SHP and we request it be deleted from the revised criteria as it would unfairly penalize these hospitals serving a disproportionate share of poor patients from being able to expand access to services.

In addition, KHA would like to point out that critical access hospitals are not included in the readmissions and mortality reporting requirement and therefore there is no data available for these facilities. Is it the Cabinet's intent to exclude these hospitals from the opportunity to expand services like Home Health which could benefit their community and long-term outcomes of patients? As the plan is written, "hospital" is not clearly defined in several section including the Home Health and Ambulatory Surgery Center. It is so loosely described that it could allow out-of-state hospitals from providing a broad range of services in this state.

Technical Notes and Common Review Criteria

KHA appreciates the Cabinet's efforts to improve upon the Technical Notes section of the SHP by ensuring the language is consistent with current CON regulation and to incorporate technical language within the specific criteria for services covered in the SHP.

KHA opposes the requirement within the Common Review Criteria for applicants to have a signed agreement with the Kentucky Health Information Exchange (KHIE) and to be both submitting and accessing data through KHIE. While acute care hospitals and some other providers have made significant strides in implementing electronic medical records (EMR), many providers have not had the same opportunities and resources to support adoption of EMRs. Specifically, federal meaningful use funding was not available for rehabilitation and psychiatric hospitals and therefore, many of these hospitals have not had the resources to adopt EMRs at the same pace as their acute care hospital counterparts. There are other non-hospital providers of services covered under the SHP that have similar challenges. KHA believes that providers intending to expand or build a service should not be unjustly prohibited from doing so because of lack of resources available to implement systems that are extremely costly to both implement and maintain. **While KHA supports the Cabinet's desire to facilitate and encourage the growth of EMRs and other valuable technology, we feel strongly that these criteria are inappropriately applied to the SHP. We ask the Cabinet to strike #2 and #3 of the Common Review Criteria.**

Comprehensive Physical Rehabilitation Beds

KHA supports allowing existing providers with Physical Rehabilitation beds the opportunity to expand their bed component if they meet utilization thresholds and quality criteria. The ability to expand services by existing providers if target occupancy has been maintained is consistent with other areas of the Plan, including the Acute Bed Need criteria. We also support use of quality metrics as a requirement for applicants to be eligible to apply. However, we have noted a problem with the proposal as it relates to quality indicators for Inpatient Rehabilitation Facilities (IRF). The CMS IRF Quality Reporting Program has been underway for several years, however, the pressure ulcer data and the catheter associated urinary tract infection (CAUTI) rate data is not yet available publicly (through a CMS Compare web site) in order for a national average to be utilized. The CMS Inpatient IRF Proposed Rule indicates that CMS plans to release this data publicly in the Fall of 2016. If the Cabinet does not want to delay the implementation of this change to the SHP and the ability of hospitals to apply for additional beds then KHA recommends the Cabinet consider allowing applicants to submit their Pressure Ulcer and CAUTI rates to the Cabinet and that those rates be compared to the published Pressure Ulcer and CAUTI national rates for acute care hospitals in the interim.

Additionally, we urge the Cabinet to change the requirement for acute care hospitals wishing to expand their bed capacity for existing inpatient rehabilitation beds be held to the same quality metrics as the free-standing inpatient rehabilitation facilities – Pressure Ulcer and CAUTI. Furthermore, applicants should be required to meet or exceed national benchmarks but should *not* be required to exceed the benchmark.

Special Care Neonatal Beds

KHA recognizes the Cabinet's effort to correct the criteria and to remove the requirement for existing providers of Level IV to have a written affiliation agreement with another Level IV facility when applying

for Level II or III beds. KHA would like to recommend a slight change in the criteria for Level III beds regarding the on-site availability of a neonatologist. The proposal includes a 15 minute requirement for on-site availability. KHA recommends this criterion be changed from 15 minutes to 30 minutes which is consistent with federal EMTALA regulations, other CMS Conditions of Participation and is also consistent with most hospital medical staff bylaws.

Long Term Care

We applaud the Cabinet for recognizing the ongoing challenge with the availability of nursing facility beds in the state and we want to particularly emphasize the challenge related to placing medically complex patients in appropriate long-term care settings. KHA supports the principle of proposed changes to the criteria to allow for the transfer of beds from one provider to another provider if quality and occupancy criteria are met. We want to emphasize that quality metrics should be reasonable so that there is appropriate opportunity for the movement of beds. There is also concern that the occupancy rate requirement coupled with the quality performance requirement could limit the ability for this transfer to take place. However, this proposed change effects only minor improvement on the continued patient placement challenges hospitals are facing. KHA has established a work group to analyze the severity of this problem and we are learning from a range of hospitals that when patients cannot be placed appropriately, hospitals must continue to care for the patient in the inpatient setting but without any payment from insurance or MCOs until a long term care facility will accept the patient. Hospitals are losing substantial money in these situations. Often patients must be placed out of state, away from family and support resources, where there is better bed availability. KHA would like the opportunity to work with the Cabinet to discuss how we can develop a system to more appropriately care for Kentuckians close to their families and support systems.

Hospitals have identified a solution to the capacity issue. Some hospitals in the state are experiencing a reduction in inpatient utilization and have beds no longer in operation. We request the Cabinet include an allowance for hospitals to convert underutilized acute care beds to nursing facility or long term care beds. KHA suggests the following language be added to the Long Term Care criteria:

> *An application to convert underutilized acute care beds to long term care beds shall be consistent with the Plan if the following conditions are met*
>
> 1. *The applicant is an acute care hospital and the occupancy of acute care beds in the facility is less than 70% according to the most recently published Hospital Utilization and Services Report, and*
> 2. *All of the proposed long term beds are being converted from licensed acute care beds, and*
> 3. *All of the long term care beds will be implemented on site at the applicant's existing licensed facility*

KHA recommends an addition to the exception under proposed section #5 to limit the transfer of beds within a planning area of the county and contiguous counties. Allowing minor exceptions to strict need criteria is an important strategy to best meet the needs of the citizens of the Commonwealth and to

improve the ability of providers to serve their populations appropriately. However, KHA strongly supports maintaining criteria, even within exceptions, to ensure that services are granted based on population and planning area based needs. Allowing services to move from one area of the state to potentially any other area within the state would depart from that overarching goal and planning strategy and could set a poor precedent for other areas of the plan.

Home Health Agency

KHA commends the Cabinet for recognizing the need for criteria to allow existing providers, especially hospitals, to provide and expand home health services to meet the long-term needs of patients. Hospitals are increasingly accountable for ensuring that patients receive effective and efficient care throughout the continuum of care. Examples of this are the CMS Readmissions Reduction Program and the Value Based Purchasing Program. Because acute care hospitals' reimbursement rate is impacted by how effective post-acute services are at preventing readmissions to hospitals, hospitals should have the opportunity to provide home health services. No other provider has a greater responsibility in ensuring that home health services are effective in improving the health of patients in an effort to prevent the need for a higher acuity patient stay either in a hospital or nursing home.

We understand the desire of the Cabinet to incorporate quality criteria within the Home Health criteria. However, we believe the criteria proposed for hospitals do not appropriately align with this particular service and should be deleted. We are particularly concerned with the use of the readmission measure for reasons already outlined. Home health services may be one of the most valuable tools for hospitals to implement in their ongoing work to effect improvement in hospital readmissions and mortality. Furthermore, hospitals with good readmission rates may actually indicate the hospital has an effective home health agency partnership established while hospitals with higher readmission rates may not have the same availability of effective services. We urge the Cabinet to delete the readmission measure from the Home Health criteria because it is flawed and will penalize the very hospitals that need home health to improve their readmission rates.

The Cabinet in two sections, Home Health and Rehabilitation Beds, has proposed a requirement for existing providers to meet national benchmarks for all 12 measures within the readmissions and mortality measure sets and additionally *to exceed the benchmark* for at least one of these measures. It is important to note that this additional factor is extremely limiting and prohibitive. Only six acute care hospitals meet this requirement according to the most recently available Hospital Compare Data. We oppose this additional requirement for any quality metric. Meeting the national benchmark should be adequate.

KHA does oppose proposed criterion #6 which would create a need criteria exemption for Accountable Care Organizations. While we understand the intent of the Cabinet is to support the health care model transformation and to enable ACOs to provide the full continuum of care in an effort to best manage the patient and outcomes, not all providers operating as an ACO have the knowledge, resources or expertise to provide Home Health Services.

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Cardiac Catheterization

KHA opposes the removal of the cardiac catheterization without surgical back-up pilot project from the criteria within the SHP. It is estimated that approximately 25% to 35% of the catheterization laboratories in the United States operate without open heart surgery back-up[1]. According to the American College of Cardiology (ACC) 2012 Consensus document, "the remarkably low risk now associated with diagnostic cardiac catheterization suggests that only a few cardiovascular patients cannot safely undergo procedures in these laboratories" and that the number of laboratories performing coronary interventions without surgical back-up has safely increased in recent years. Furthermore, there are only a few exceptions which include patients with complex congenital heart disease and pediatric patients, which should be treated only in full-service facilities.

As the ACC indicates, programs providing interventional cardiology without open heart back-up have been growing nationwide safely in recent years. Kentucky implemented the current pilot program following a very thoughtful and scientifically based pilot approach based on appropriate selection criteria and evaluation of outcomes. The program has received strong support and approval from tertiary facilities affiliated with the programs as well as from Dr. Layman Gray who evaluated the initial pilot project on behalf of the Cabinet to help determine safety and efficacy.

Included in the existing pilot process, through 900 KAR 6:120, are numerous quality assurance mechanisms to ensure a pilot hospital is performing at high quality standards and that outcomes are safe and effective. The regulation also provides the Cabinet's Office of Health Policy numerous opportunities to intervene if there are any concerns related to quality:

- Reporting of death and adverse events by hospitals within established timeframes
- Joint Performance Improvement Committee with collaborating tertiary hospital that includes a requirement for the development and implementation of a plan of correction if problems are identified.
- Review of the pilot hospital performance by an outside evaluator including a university affiliate
- The ability of the Cabinet to terminate a trial if outcomes warrant termination.

There is ample opportunity within the existing SHP criteria and 900 KAR 6:120, the licensure regulation on pilot hospitals, to closely monitor pilot hospitals providing cardiac intervention services to ensure an appropriate level of quality and to intervene when reporting and outcomes indicate a hospital is not meeting established standards.

This pilot program was established to provide improved access and life saving treatment to Kentuckians – 45% of which live in rural areas – suffering from acute myocardial infarction. Kentucky looked to other states, more advanced in expanding this service outside of surgical back-up including Massachusetts, and to published guidelines from the ACC – when creating this pilot. The consensus in the industry is

[1] 2012 American College of Cardiology Foundation/ Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

that it is safe to practice interventional cardiology without open heart surgery back-up if ACC guidelines are practiced closely and there is a level of quality assurance monitoring. The existing program within the SHP aligns with this recommendation.

There are a number of hospitals in the state which have been working to build their diagnostic programs into interventional programs. These facilities have invested significantly in technology, education, staffing and other resources in the effort to best meet the health care needs of their community. At a time when most every state has moved or is in the process of moving to allow this, it does not make sense that Kentucky proposes changes to the SHP which would move us backwards, away from the most effective and innovative model of care for patients with life-threatening conditions.

KHA strongly encourages the Cabinet to withdraw the proposal to eliminate the pilot angioplasty program from the SHP criteria. We welcome the opportunity to work with the Cabinet to review the existing collaborative relationship requirements, review standards and reporting processes to determine if there is a need for improvement upon existing procedures. The value of pilot programs is the ability to improve upon processes and ultimately outcomes.

Magnetic Resonance Imaging Equipment

KHA opposes the proposal to eliminate need criteria for establishing Magnetic Resonance Imaging Equipment or MRI. KHA understands that MRI is a widely available and utilized service in many health care settings. Since 2009 there has been approximately 17 approved out of 20 MRI applications. This is an indication that the MRI criteria within the SHP is being appropriately applied and that all applications which are reasonable are accepted.

However, there are ongoing concerns about quality of services, particularly the quality of the magnet in equipment. The primary concern of the members is in regards to the lack of quality equipment in some outpatient settings. The potential for this to become a growing problem in Kentucky if MRI is removed from the formal review process has been observed in facilities in border state communities. Many members have observed that MRI centers established outside of CON programs in bordering states have low quality scanners. When Kentucky-based physicians try to read the results from these MRI procedures for patients who have gone to low cost/low quality centers, the quality of the scan does not allow the physician to act or treat on quality and reliable information. This often results in the need for a repeat scan by a higher quality machine. Therefore, the result is duplication of health care services to ensure the appropriate level of quality and ultimately an increase to health care costs. The SHP criteria at the very least establishes a requirement for applicants to ensure there is a need for the equipment and that equipment will meet a minimum level of quality. We urge the Cabinet to maintain MRI under the formal review process. The formal review process also assures the quality in the interpretation of the scans because applicants must specify the credentials of the physicians. We offer the opportunity to discuss with the Cabinet the opportunity to promote a standard level of quality for equipment through licensure.

Even accrediting organizations, like the American College of Radiology (ACR) recognize specific levels of quality for both magnets and for physicians interpreting the results. The Cabinet should look to these organizations and ensure any changes would be in keeping with the appropriate level of quality established by such organizations.

An alternative approach to allowing MRI to expand would be to have an exception to criteria which requires accreditation from the American College of Radiology (ACR) by applicants. One accreditation requirement is that a minimum magnet quality be in place.

Megavolt Radiation Equipment

We appreciate the Cabinet addressing the ongoing problem both the Cabinet and providers face with CON approved but not licensed health services. The proposed changes to address this consists of a change to the Megavoltage Radiation Therapy Program definition to include *only licensed centers and CON approved but not licensed within the previous three years.* While we support this effort to ensure that applicants are not penalized by programs which have been approved but not implemented, we believe there is a more appropriate way to address this ongoing problem. We encourage and support the Cabinet in actively monitoring Progress Reports and we believe that the Cabinet should revoke applications for programs which do not demonstrate progress toward full implementation within an appropriate timeframe. KHA believes that the proposed definition language could set an unwanted and unnecessary precedent for other services and could adversely impact other applicants for large-scale projects which are making steady progress. We encourage the Cabinet to remove this definition and to address the ongoing issues by vigorously reviewing CON Progress Reports and revoking Megavolt Radiation Equipment CONs for applicants which have not made progress in three years or more.

KHA does not support the exception to the need criteria within proposed criterion #3. We firmly believe there should be need-based criteria for Megavoltage Radiation Equipment. Additionally, the proposal would seemingly allow an out-of-state hospital to establish this equipment anywhere in the Commonwealth. Because radiation treatment is a costly and highly technical service, Kentucky should aim to ensure applicants are Kentucky-based providers and that applicants should be held to population based need criteria within the defined planning area because it will decrease volume at existing providers which will increase overall cost of care.

Ambulatory Surgery Center

KHA strongly opposes exceptions to population based need criteria to establish an Ambulatory Surgery Center (ASC). We would like to reference the 2014 KHA study "CON: Stabilizing Force for Healthcare Transformation" which was submitted to the Cabinet for consideration in December 2014 during the open comment period on CON Modernization.

> *"[The] Kentucky General Assembly has twice weighed in on the issue of ASCs. Legislation was passed in 2012 clarifying legislative intent by specifically mandating that ASCs be required to obtain a CON. Then, in the 2014 legislative session, the Kentucky General*

Assembly took action to assure that CON review for ASCs would be conducted under the formal review process by requiring that the State Health Plan contain specific review criteria that is based on population need. In taking these actions, the General Assembly recognized the importance of CON in assuring quality and access as it relates to outpatient surgery.

Recommendations for altering or loosening the ASC criteria are based on unreliable information. Data published by the Cabinet annually in the Utilization and Services Report indicate there is ample capacity within existing ASC and hospital outpatient departments to provide services throughout the state. The data published in the Deloitte Healthcare Facility Capacity Report regarding ASCs is neither reliable nor replicable and therefore should not be used to guide any policy changes.

KHA conducted a survey in October 2014 of hospital outpatient surgery departments and ambulatory surgery centers. We learned there are a number of available surgical suites not in use primarily because there is a lack of demand for procedures and secondarily due to surgeon availability. Data indicate there is even greater capacity available to meet need in the immediate future. Additionally, 85% of responders indicated they have the ability to flex their hours of operation to meet patient demands if and when those change. Forty-four percent (44%) of responders report they flex hours to meet needs on a regular or weekly basis. Finally, 89% of responders indicated their scheduling lead time was two weeks or less, a clear indication there are not long waits for outpatient surgical procedures. Only 2% indicated a wait time of greater than one month. And responders indicated the primary driver of wait time or "lead time" is physician preference or availability.

When we evaluate outcomes in other states where CON was revoked or ASC criteria was eliminated, we have learned that there is gross proliferation of ASCs, there are documented incidences of cherry-picking by profit-seeking providers and investors and there are adverse impacts to community and safety-net hospitals which are left to provide care for only the sickest patients and those with poor insurance reimbursement. A recent study published by State Auditor Adam Edelen illustrated the ongoing financial challenges many rural Kentucky hospitals continue to encounter. Allowing ASCs to be established by any hospital (including out-of-state) virtually anywhere in the Commonwealth will have detrimental impacts to the existing hospital providers fighting to provide a full range of services to all patients regardless of their ability to pay.

If the goal of the Certificate of Need program is to ensure there is access to quality health care services, to contain health care costs and to prevent the unnecessary duplication of services, then the recommendations to provide criteria exemptions to the ASC criteria within the SHP are in direct conflict with the intent of the CON program. The existence of ample capacity within ASCs and outpatient departments of hospital surgical programs as published by the Cabinet indicates there is no significant need for additional outpatient surgical capacity. Criterion #5 offers an exemption for applicants with a majority hospital (even a non-Kentucky hospital as written) ownership to establish and ASC anywhere within the state if quality metrics are met. There are a number of problems with this recommendation:

- This would allow non Kentucky hospitals to establish an ASC in Kentucky
- This would promote cherry-picking
- There is no reference or requirement to establish the ASC within the established planning area – the county and contiguous counties. As discussed previously, the SHP should maintain the use of planning areas in keeping with the intent of the CON program to provide community level planning and access to care.
- The quality metrics included in the requirement, readmissions rate and mortality rate, are related to mostly non-surgical *inpatient* care and are not a good measure of quality related to outpatient services.

The proposal under criterion #6 would allow the private office of a physician or physician group which is 100% owned by those physicians to apply to establish an ASC if they have been operating for ten years and they are proposing to do surgical procedures which they have performed for the previous five years in their office. There are numerous problems with this proposal as well. If the physician(s) has an established office where it has already been performing the procedures it is proposing to perform in an ASC in its office for five years then the proposed change does nothing to address an identified need, improve quality or contain costs. In fact, it would increase costs to health care because it would merely increase the reimbursement to the physician by adding a facility fee to the payment for procedures already being performed on existing patients. The proposal does not adequately address quality risks associated with performing surgical procedures in a physician office. What would prevent a physician with an established ASC from expanding the procedures performed in the ASC outside those performed in their office in the last 5 years? Additionally, there are numerous reports nationally, including some high-profile reporting, of procedures with bad outcomes in ASCs. The leading factor to these adverse outcomes and sometimes death is often use of anesthesia without proper training, experience and/or monitoring.

KHA strongly supports maintaining the ASC criteria as is written in the current plan, including maintaining language to require ASCs to have transfer agreements in place with receiving hospitals within 20 minutes of the ASC. Existing language in the state budget requires a population based need criteria to be used in the *review* of CON applications for ASCs. The proposed changes are in direct conflict with that language as they provide a mechanism for review for ASC approval nothwithstanding the need criteria. Finally, we oppose the changes based on use of inappropriate quality metrics and potential for establishment of ASCs by out-of-state providers virtually anywhere within the Commonwealth of Kentucky, even in counties where an ASC is already operating.

Chemical Dependency

KHA opposes the Cabinet's proposal to remove Chemical Dependency beds from the SHP and the formal review process. The KHA Psychiatric and Chemical Dependency Hospital Forum (Psych and CD Forum) represent providers of both free standing hospitals and acute care hospital-based psychiatric and chemical dependency units. Members of the Forum have been meeting regularly to discuss the changing policy around expansion of care for patients suffering from chemical dependency. The KHA and our members are glad to continue to work with the Cabinet to revise the existing criteria for chemical

dependency need criteria to be in keeping with current practice trends and best practices but we feel strongly that chemical dependency beds must remain under the formal review process.

Historically, there is consensus among KHA members that we may benefit from improving the SHP criteria to better reflect current utilization and practice models. It should be noted that current models for treating patients with chemical dependency diagnoses include an extensive continuum of care. Specifically, there are a full range of services, within multiple provider settings, that must be included when we consider and plan for our current and future chemical dependency treatment needs. Within these services are medical detoxification, inpatient treatment, partial hospitalization programs, intensive outpatient programs, residential treatment facilities and other levels of care that are included in the best practice models.

We understand that the impetus for the Cabinet's proposal to remove the Chemical Dependency Bed need criteria from formal review was legislation recently passed by the General Assembly – SB 192. The legislation created a CON exemption for the establishment of *free-standing residential substance use disorder treatment programs* limited to 16 beds. These residential facilities, for which there is no licensure regulation at this time, should not be confused with inpatient chemical dependency treatment.

The Inpatient hospital chemical dependency beds are considered to be an acute inpatient level of care – not residential care – which are used to provide medical detoxification for drug and alcohol dependency and have a short length of stay. While the type of facility that is outlined in SB 192 is not yet defined in Kentucky regulation, residential facilities in general are very different from inpatient chemical dependency beds, which follow a medical model. Residential facilities typically provide 28 day counseling programs, often not providing medical oversight and supervised detoxification. It is imperative to keep the chemical dependency treatment beds in CON because these are acute hospital beds and complete deregulation would have a detrimental impact on existing providers by potentially reducing volume and allowing for cherry-picking of the most well-insured patients.

Outpatient Health Center

KHA is opposed to the Cabinet's proposal to remove Outpatient Health Care Center from the SHP and the formal review process. We understand that the category and supporting criteria are currently specific to only one community which already has established the facility. However, we are concerned that removing this component from the SHP would allow these centers to potentially be established anywhere in the state by anyone with only minor changes to the existing licensure regulation. The existing licensure regulation allows an outpatient health center to provide 24 hour emergency services, primary care, radiology, MRI, and ambulatory surgery – essentially a hospital without beds. Although the current licensure regulation restricts the center to a county with a population of 60,000, removal of that provision would allow these centers to be built anywhere. These centers could function as an outpatient hospital without meeting hospital requirements such as EMTALA and therefore could threaten the existence of Kentucky's rural hospitals. Furthermore, ASC and MRI are separately covered in the SHP under distinct review criteria. Under the Boone Spring decision, no service can be covered

under non-substantive review for which there is a component under the SHP. Because ASCs and MRIs are under formal review, the Outpatient Health Care Center cannot be reviewed under non-substantive review.

As previously discussed with the Cabinet, KHA and our members do support the ability of existing hospital providers with declining inpatient volume threatening their long-term financial integrity to have a mechanism to *seamlessly* convert, without having to close completely, into an Outpatient Health Center. This would allow for the continued access to primary care, emergency services and ambulatory surgical services within the community. There are a number of federal demonstration projects for similar models being conducted by the Centers for Medicare and Medicaid Services. Additionally, there have been at least two bills introduced in Congress to offer alternative care delivery models for small and rural hospitals. We believe as we continue the transformation of the healthcare delivery model in future months and years, there may be Kentucky hospitals that could benefit from a model of this nature. Therefore, KHA supports retaining the Outpatient Healthcare Center component in this SHP and revising it to apply to the conversion of existing acute care and critical access hospitals to a center located in the same county as the hospital.

MEDNAX
NATIONAL MEDICAL GROUP

AMERICAN ANESTHESIOLOGY

PEDIATRIX MEDICAL GROUP

June 30, 2015

Ms. Tricia Orme
Office of Legal Services
Cabinet for Health and Family Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Re: Proposed Amendments to the State Health Plan

Comments Via Email: tricia.orme@ky.gov

Dear Ms. Orme:

On behalf of Pediatrix Medical Group of Kentucky, P.S.C. ("Pediatrix"), we appreciate your commitment to drafting the 2015-2017 State Health Plan ("Plan") and commend your efforts to ensure that quality healthcare services are provided to Kentucky residents. Pediatrix is pleased to submit these comments on the draft Plan.

Pediatrix is a Kentucky practice group providing services in neonatology at Baptist Health in Lexington. Pediatrix is also related to Pediatrix Medical Group, Inc., a division of MEDNAX, Inc., a national medical group comprised of more than 2,675 physicians in 34 states and Puerto Rico. MEDNAX, Inc., through its affiliated practice groups, provides neonatal, anesthesia, maternal-fetal, and pediatric physician subspecialty services. Our organization strives to improve patient outcomes and to offer high-quality, cost-effective care through the use of evidence-based tools, continuous quality initiatives, and clinical research.

Pediatrix supports the Plan's desire to ensure delivery of quality high risk neonatal care in Kentucky, but we would like to highlight the following areas of the proposed Plan that we recommend be modified to better align with national guidance while maintaining high quality standards:

> Proposed section I(D)(III)(3)(b): *A neonatologist who is continuously available 24 hours per day and able to be on-site within fifteen (15) minutes.*
>
> Proposed section I(D)(III)(3)(c): *A neonatal advanced practice registered nurse with training and skills specified in the most recent published edition of the Guidelines for Perinatal Care, or a fellow in an approved Neonatal-Perinatal Medicine Fellowship shall be on-site and continuously available when a neonatologist is not on-site.*

We recommend deleting or revising these statements to be consistent with nationally published guidance while still maintaining the high level of urgent response required of the level III unit. For example, with regard to placing a time threshold on level III neonatologist availability, the *Guidelines for Perinatal Care*, published by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) notes that "*...a neonatologist should be continuously available*

for consultation 24 hours per day. Personnel qualified to manage the care of mothers or neonates with complex or critical illnesses, including emergencies, should be in house."[1] Thus, there is recognition that multiple members of the care team contribute to urgent care and that while the neonatologist must be available, physical presence time thresholds do not necessarily contribute to improved care so long as qualified care team members are otherwise physically present who are capable of emergently responding. Furthermore, the 15 minute threshold has no historical basis in supporting improved outcome in an emergency. For example, ACOG has historically advocated that in one such life threatening scenario (emergency caesarian section with fetus at risk), 30 minutes was reasonable from the perspective of decision to incision. More recently, even ACOG has discouraged placing any time threshold on such emergency presence by noting that *"...scientific evidence to support this threshold is lacking"* and encourages facilities to tailor such emergency time to local circumstances and logistics.[2]

Widely acknowledged publications such as Guidelines for Perinatal Care as well as the American Academy of Pediatrics' policy statement *Levels of Neonatal Care*[3] demonstrate that for level III care, while the neonatologist must be continuously available, the healthcare team's skill, training, and experience can represent a capability of responding to emergencies just as immediately effective, regardless of in-house presence of a neonatologist or nurse practitioner. Such nationally recognized publications do not mandate either neonatologist or nurse practitioner in-house presence, but rather focus on each hospital's capability to ensure presence of a highly trained staff covering a broad range of responsibilities. Furthermore, for those personnel assigned to in-house coverage, the designation spans a greater range than solely a nurse practitioner or neonatal fellow and at least also includes pediatricians such as pediatric hospitalists.[4]

The Plan's facility, service, and equipment requirements for Level III are consistent with national guidelines. Pediatrix strongly recommends that the personnel requirements for a Level III facility also represent national guidelines. Therefore, Pediatrix urges the Cabinet to delete the Plan's proposed Sections I(D)(III)(3)(b)-(c) to its Level III requirements, or revise them to be consistent with nationally published guidance, as discussed above.

We would also highlight our recommendation regarding the following proposed Plan requirement:

> Proposed section I(D)(III)(3)(l): *Documentation of the facility's participation in the Vermont Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within their facility and to compare with other levels.*

We agree that participation in a robust database allows for necessary benchmarking of neonatal morbidity and mortality, but we suggest that the Plan accommodate local discretion in selection of a representative database. For example, the Pediatrix Medical Group Clinical Data Warehouse is one of the largest

[1] Guidelines for Perinatal Care, 7th edition, AAP, ACOG, 2012, p26.
[2] Ibid, p192.
[3] Levels of Neonatal Care, AAP Committee of Fetus and Newborn, Pediatrics 2012; 130: 587-597.
[4] Guidelines for Perinatal Care, 7th edition, AAP, ACOG, 2012, p22.

repositories of neonatal data representing over 11,000,000 patient days and encompassing approximately 200 neonatal practices in 33 states.[5] Large databases such as either the Vermont Oxford Network or the Pediatrix Clinical Data Warehouse allow the neonatal unit to track important areas of morbidity and mortality and to benchmark against peers, and we suggest that respective neonatal groups and their hospitals be granted discretion in database choice. Pediatrix proposes that the language be amended to include not only VON, but also the discretion for hospitals to use similar large-volume registries or databases to allow for a more comprehensive and complete set of benchmarking data.

Our organization supports policies aimed at improving and providing high quality healthcare services and we thank you for your timely consideration of this matter. Please let us know if we can provide any further information or help answer any questions.

Sincerely,

Robert J. Balcom, M.D.
President
Pediatrix Medical Group of Kentucky, P.S.C.

[5] Spitzer et al. The Pediatrix BabyStepsData Warehouse and the Pediatrix QualitySteps Improvement Project System—Tools for "Meaningful Use" in Continuous Quality Improvement. Clinics in Perinatology 2010; 37: 49-70.

UKHealthCare

June 30, 2015

Emily Parento
Executive Director
Office of Health Policy
275 East Main Street, 4W-E
Frankfort, KY 40621

RE: 2015 – 2017 State Health Plan

Dear Ms. Parento,

This letter is in response to your request for public comments related to the May 2015 draft *2015 – 2017 State Health Plan* ("SHP"). UK HealthCare appreciates the opportunity to comment on potential Certificate of Need modernization efforts and agree that modernization efforts may be beneficial in order to meet the Cabinet's primary vision of achieving the Triple Aim, as well as in many of the Cabinet's stated core principles.

Once licensed, there is no state regulatory mechanism to ensure that the applicant's projected procedure/patient volumes are met, which may lead to potential quality issues. If market factors change, or there are unexpected workforce challenges which prevent the facility from meeting their volume projections, the provider still maintains the licensure authority to continue providing these services.

The SHP attempts to address this issue with respect to existing facilities with diagnostic cardiac catheterization services who propose to also provide primary and elective Percutaneous Coronary Intervention (PCI) services. Only upon successful completion of 2 year pilot program will the cabinet provide permanent licensure authority. This model holds providers responsible for maintaining standards of volume and quality, or risk revocation of their licensure authority to continue providing these services.

Although expansion of the pilot program process to other specialty and tertiary service lines would add to the administrative duties of the Cabinet, UK HealthCare believes it would be helpful in influencing and improving health outcomes for Kentuckians. While future applicants may be at a risk for losing their licensure authority to continue providing these services, we believe the overall effect of improved quality and health outcomes far outweighs the negatives. In response to the Cabinet's proposed changes to the SHP and in order to better enable health care

Hospital Administration

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providers to work towards improving health for all Kentuckians, UK HealthCare suggests the following:

Ambulatory Surgery Center

It is the position of UK HealthCare that the proposed exception may also apply to out-of-state hospitals that are desirous of establishing an ASC. This unusual exception would negatively impact Kentucky's existing acute care hospital network by granting special treatment to out-of-state providers who can selectively choose their patient populations, payor mix and surgical procedures without the additional administrative and infrastructure expenses associated with operating an acute care hospital within the Commonwealth of Kentucky.

NICU

UK HealthCare is supportive of the elimination of the requirement for Level II and III providers who also meets Level IV criteria to no longer require a written affiliation agreement with a provider who meets Level IV criteria.

It is our understanding that the Cabinet also modified the criteria for a Level III provider to no longer require a neonatologist be on-site 24 hours per day but would allow that provider to be 'continuously available 24 hours per day and able to be on-site within fifteen (15) minutes.' While the Guidelines for Perinatal Care are not completely specific, they do state that Level III providers are those "having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists)...".

UK HealthCare is supportive of the Cabinet's recommended change. However, since these programs care for our most fragile infants it is imperative that the time for a neonatologist to be on-site not extend beyond the proposed 15 minute threshold.

Megavolt Radiation

It is our understanding that the proposed criteria #3 would allow an exception for any hospital that meets one of the accreditation criteria irrespective of need as calculated by the SHP.

Since the planning area for determining consistency with the SHP is limited to Kentucky counties, it is the position of UK HealthCare that any exception to the criteria for acute care hospitals should be limited to acute care hospitals located within the Commonwealth of Kentucky. Not doing so would open our borders and potentially allow a significant number of providers with less than altruistic

intentions to add services in Kentucky without demonstrating consistency with the need formula set forth in the SHP.

Services Removed From the State Health Plan

UK HealthCare is supportive of removing the following categories of care from the SHP:

- Adult Day
- MRI
- Miscellaneous
- Chemical Dependency Beds

That said, UK HealthCare recommends a cautious approach to the expansion of Outpatient Health Centers ("OHC"). These facilities were previously restricted to counties with a population of at least 60,000 Kentuckians, no existing acute care hospital and located in a medically-underserved area as determined by the Secretary of the Federal Department of Health and Human Services. By removing this category from the SHP, an applicant could potentially receive CON approval to establish an OHC where no need exists. A more thoughtful approach would be to allow struggling acute care hospitals and/or critical access hospitals to transition to an OHC without first requiring the facility to close. A more seamless transition to this lower level of care could ensure that emergent health care services remain available to serve their populations.

Rehabilitation Facility, Long-Term Care, and Home Health.

UK HealthCare is supportive of the Cabinet's efforts to increase acute post-discharge treatment options for our patients.

In conclusion, it may be beneficial for the Cabinet to commission an independent study tasked with providing recommendations to modernize the CON program in an attempt to satisfy the triple aim. To our knowledge, the most recent research memorandum regarding CON was published in August 1989 by Karen Main at the request of the Interim Joint Committee on Health and Welfare. Although the Cabinet does frequently cite the recommendations and conclusions published in the Deloitte Workforce Analysis, it is our understanding and belief that their recommendations related to CON modernization are merely anecdotal and do not fully contemplate and/or comprehend the effect of drastically increasing the volume of providers upon our current health care delivery system. A more complete and thoughtful analysis of current health care financing and access trends would be desirable prior to any attempts to significantly alter the health care provider landscape.

Sincerely,

Mark D. Birdwhistell
Vice President for Administration and External Affairs

KentuckyOne Health™

June 30, 2015

Tricia Orme
Office of Legal Services
275 E. Main St. 5 W-B
Frankfort, KY 40601

Re: 900 KAR 5:020
2015-2017 State Health Plan

Dear Ms. Orme:

I am writing on behalf of KentuckyOne Health and its affiliated companies to express our comments on the proposed changes in the 2015-2017 Kentucky State Health Plan. KentuckyOne is the largest healthcare provider in Kentucky. KentuckyOne and its affiliates operate nine acute care hospitals, two critical access hospitals, one psychiatric hospital and one comprehensive physical rehabilitation hospital in Kentucky. These range from large, tertiary hospitals in Louisville and Lexington to critical access hospitals in Berea and Martin. We also operate numerous outpatient facilities and are affiliated with three different home health agencies through our parent organization Catholic Health Initiatives. We have more than 15,000 employees in Kentucky.

KentuckyOne and our predecessors have long supported Kentucky's Certificate of Need program and worked with the Cabinet and its predecessors in the health planning process. We are very concerned that some of the proposed changes will reduce quality of care, harm existing providers, especially rural hospitals, and lead to an unnecessary proliferation of unneeded health facilities and services.

GENERAL COMMENTS

We are concerned that several of the proposals will harm quality of care. As a general rule, we suggest that the Cabinet make no change unless it can be demonstrated that the change will improve quality of care. While we support the Cabinet in including quality standards in the State Health Plan, many of the proposals rely on benchmarks that are not related to the service or facility being proposed in an application. For example, how do mortality rates for stroke patients relate to a hospital's ability to establish a quality ASC? To the extent that the Cabinet decides to include quality benchmarks, they should be directly related to the services under review and we ask that the Cabinet engage providers in assisting in determining the appropriate metrics for these services.

In addition, we would like the Cabinet to consider exceptions for our state's Academic Medical Centers. These institutions are tremendous assets to the state of Kentucky, and the Cabinet would be doing the state and its citizens a disservice if these institutions are not given special

consideration, given the value they bring to the state. They provide access to the latest technology and cutting edge research to improve care; and they are the training grounds for future health care professionals who will likely stay within the state after completion of their training. These health care professionals will be charged with ensuring the health of the citizens of the Commonwealth now and into the future. In addition, Academic Medical Centers care for all patients regardless of their condition, the complexity of their medical needs and their ability to pay. Academic Medical Centers are unique state assets that must have the flexibility to thoughtfully disperse their models of care throughout the region to meet patients where they are, and to provide access to cutting edge research and higher levels of care.

SPECIFIC SERVICES

I. Ambulatory Surgical Center

We oppose the Cabinet's proposed Ambulatory Surgical Center Review Criteria 5 and 6 at page 60 of the 2015-2017 Kentucky State Health Plan. These criteria create two potentially very broad exceptions that could easily lead to a proliferation of unneeded ASCs and could lower the quality and raise the cost of outpatient surgery services.

Proposed ASC Criterion 5 would make applications by certain hospitals, or entities with >50% ownership by those hospitals, automatically consistent with the SHP. It does not limit the number or location of ASCs to be established. It does not take into account any factors concerning the need for another ASC in the area or true quality of the service being provided by the applicant. On its face, it appears that it would even apply to out-of-state hospitals proposing ASCs in Kentucky.

If the Cabinet were to decide to keep a version of Criterion 5 in the Plan, it should be limited to Kentucky hospitals and should have geographic limitations. Further, any quality indicators should specifically relate to the services being proposed (e.g. outpatient surgery patients receiving their antibiotics at the right time).

Proposed ASC Criteria 5 and 6 do not specifically address geographic need and quality related to ambulatory surgery and should be revised to consider geographic need and applicable quality criterion to ensure that ASC's are only established where they are needed and that only quality providers are given the opportunity to establish ASC's. This would reduce the negative impact on Kentucky Hospitals, particularly those that are located in rural areas. It is well documented that many Kentucky hospitals are at risk of failing. Being burdened with the high cost of 24-hour services, indigent care, governmental programs paying less than cost, and other

serious threats to their solvency, hospitals cannot afford to have more ASCs syphoning off some of the last remaining profitable services.

For all of these reasons, we request that the Cabinet delete proposed ASC Review Criteria 5 and 6 or consider engaging providers to develop revised criteria based on geographic need and applicable quality indicators.

II. MRI Services.

We oppose the Cabinet's proposal to remove MRI criteria from the 2015-2017 Kentucky State Health Plan. Again, this opposition is based upon quality concerns as well as the threat to existing providers, especially rural hospitals. Because of the statutory CON exemption in KRS 216B.020(1) for diagnostic centers that do not provide SHP covered services, removing MRI from the Plan would effectively remove any CON requirement for MRI facilities.

The Cabinet's proposal would constitute another opportunity for others to skim some of the last remaining "cream" off the top and greatly jeopardize struggling hospitals. Anyone could establish a free-standing diagnostic center with MRI next door to any hospital, without any showing of need or the ability to provide a quality service.

The MRI criteria in the State Health Plan have not precluded approval of needed MRI services. However, they do make applicants demonstrate a need and ensure a minimum quality. In the last five years, there have been a number of applications for new services that were approved. However, there have been three that were disapproved. Of those, two were disapproved based upon an inconsistency with all statutory criteria, including need and quality of services. Indeed, the CON requirement has been useful in preventing poor quality providers from establishing MRI services and should remain in the plan to ensure that poor quality providers are excluded from providing these services. The Cabinet should keep MRI in the State Health Plan.

III. Megavoltage Radiation Equipment.

The Cabinet has proposed several changes in the radiation oncology review criteria. We request that the Cabinet modify proposed Review Criterion 3 at page 53 of the 2015-2017 Kentucky State Health Plan. Review Criterion 3 proposes exceptions to the need methodology for applications by certain hospitals, or entities owned >50% by those hospitals. Our review indicates that there are currently as many as seventeen hospitals that would fall within these exceptions. That number could increase in the future.

We propose that the Cabinet change proposed Review Criterion 3 so that it applies only to applicants owned at least 50% by hospitals that are accredited by the American College of Surgeons Commission on Cancer as an Academic Comprehensive Cancer Program. Not only will this help ensure quality and remove the real possibility of the proliferation of unneeded programs, it will also allow patients to access comprehensive, multi-disciplinary cancer care and clinical trials closer to their homes.

IV. **Special Care Neonatal Beds.**

We operate hospitals that provide Level II and Level III neonatal services. At pages 13 and 15 of the 2015-2017 Kentucky State Health Plan, the Cabinet has proposed clarifying language confirming that a Level IV provider that wishes to add Level II or Level III beds need not have an affiliation agreement with a Level IV provider. We support this change.

At pages 13-14, the Cabinet is proposing changes in Review Criterion 3. Criterion 3b would require an applicant for Level III beds to document that it has a neonatologist available 24 hours per day who is "able to be on-site within fifteen (15) minutes." We support this change, except that in many cases it may be very difficult to have a neonatologist who can be on-site within fifteen (15) minutes. Many hospital bylaws require that emergency room physicians, interventional cardiologists, etc. be on-site within thirty (30) minutes. We request that the Cabinet change this proposal to require that Level III applicants demonstrate that a neonatologist is able to be on-site within thirty (30) minutes.

Criterion 3c would require that applicants for Level III beds demonstrate that they will have a neonatal APRN on-site at all times when a neonatologist is not on-site. We support this change.

V. **Long-Term Care.**

The Cabinet has proposed adding a Review Criterion 5 to the Nursing Facility beds criteria. This would authorize, in limited circumstances, transfers of NF beds between facilities located in different counties. We propose that the Cabinet make an additional change that would allow acute care hospitals and comprehensive physical rehabilitation hospitals to convert a limited number of their acute or rehab beds to nursing facility beds. This is necessary as the aging population increases and many more patients begin to need skilled nursing care. In addition, many patients in need of single joint replacement and other short-term rehab stays do not qualify for a stay in an inpatient rehab facility however are in need of short-term rehab care and education on how to function with a joint replacement. Finally, as health systems move toward

population health management and bundled payments for these types of procedures, it is important that health systems have the opportunity to control the quality and cost of the care for the patient population for which they are responsible. Allowing health systems to convert acute care or rehab facility beds to nursing facility beds would give them the opportunity to improve outcomes and reduce possible complications related to patients in need of short-term rehabilitation.

VI. Comprehensive Physical Rehabilitation Beds.

The Cabinet has proposed adding a Review Criterion 6 to the Rehab Bed methodology. This would authorize existing facilities with rehab beds to add beds if their occupancy exceeds 80% and they meet certain quality benchmarks. We generally support program expansion based upon quality and high occupancy. However, the quality metrics for acute care hospitals with rehab beds should be related specifically to rehab patients and services, not hospital-wide metrics unrelated to rehab.

VII. Home Health Agency.

The Cabinet has proposed adding Review Criteria 4, 5 and 6 to the home health criteria. Criterion 4 authorizes certain hospitals to establish home health agencies. Criterion 5 allows certain home health agencies to expand their service areas. Criterion 6 allows ACO's and their affiliates to establish or expand home health agencies.

We support the concept in Criterion 4. However the quality metrics related to hospital readmission rates and hospital mortality are not related to the hospital's ability to provide quality home health services. Indeed the hospital readmission rate may be inversely proportional to the need for a new home health agency.

We support proposed Criterion 5 and agree that the metrics are directly related to quality.

We support the proposed Criterion 6, which would authorize ACO's and their affiliates to establish or expand home health agencies. This will allow providers to improve quality, cost and access to care and have better control over the full continuum of care.

VIII. Hospice Services.

The current CON regulatory process is a serious hindrance to the development of hospice services as part of a robust continuum of care. Of Kentucky's 120 counties, 87 have only one licensed hospice provider. The current State Health Plan methodology precludes approval of a second provider in 85 of these 87 counties. In order to allow health systems to further develop

the continuum of care to best serve the patient population, Hospice Service Criterion should be relaxed. As Criterion 6, in the proposed revised State Health Plan allows ACO's and their affiliates to establish or expand home health agencies, KentuckyOne is asking that the same request be incorporated into the Hospice Service Criterion as Criterion 3. Again, this will allow providers the opportunity to improve quality, cost and access to care by allowing them to exercise control over the full continuum of care. In addition, this would offer patients a choice of provider, which is currently lacking in this area of health service.

IX. Outpatient Health Care Center.

The Cabinet has proposed deleting the criteria for Outpatient Health Care Center from the 2015-2017 Kentucky State Health Plan. As the operator of a licensed Outpatient Health Care Center, we oppose this change. There is a license category for this type of facility. If the review criteria were removed from the Plan, it could lead to confusion and the unintended consequence of applicants seeking nonsubstantive review to create new facilities even though they could not comply with the licensure requirements.

As an alternative, we request that the Cabinet leave these criteria in the Plan, but also establish a new licensure category specifically designed for the conversion of hospitals to outpatient facilities under nonsubstantive review. As health care is evolving and ambulatory health care is accelerating, there is less need for inpatient facilities, particularly in rural areas with low population density. While there is a definite need for citizens to have access to care in these areas, inpatient facilities may not continue to be feasible. As rural and critical access hospitals become less sustainable, there is a need to create a pathway to allow some inpatient facilities to continue to operate in an outpatient capacity to meet the needs of the community. However, there is a need for these facilities to still have the ability to re-open as an inpatient facility in the future if changes in health care or population trends create the need to do so. The Cabinet should consider creation of a regulation that will allow acute hospitals to convert to outpatient facilities, maintain all existing outpatient services, as well the ability to "bank" the facility's existing beds to allow conversion back to an inpatient facility in the future if necessary.

CONCLUSION

Thank you for the opportunity to submit these written comments. As always, we support Kentucky's CON program and will continue to work with the Cabinet in the health planning process.

Sincerely,

Adonna Wickliffe
Director of Strategy
KentuckyOne Health

GRAVES GILBERT CLINIC

June 9, 2015

Ms. Tricia Orme
Cabinet for Health and Family Services
Office of Legal Services
275 East Main Street, 5W-B
Frankfort, KY 40621

Dear Ms. Orme:

On behalf of the nearly 140 physicians and nurse practitioners at Graves-Gilbert Clinic, and the over 300,000 patient visits we provided in 2014, we are writing to express our **absolute support for the administrative regulation amendment to 900 KAR 5:020.**

For almost 80 years, we have been the overwhelming provider of healthcare services to the Medical Center and the citizens of South Central Kentucky. Since 1974 there have been many changes in healthcare. However the need for better access to quality, low cost patient care remains constant.

Assumptions and guidelines used in the last few decades have grown to be outdated and obsolete. Plans that initially were designed to support services have now created unnecessary constraints on competition. These barriers have in essence created monopolies that **result in inefficient and higher cost health services.** Attempts at creating alternative, competitive services are met with heavy handed responses.

Unfortunately, CON rules that started with noble intentions are now used to unduly protect territory and prop up prices. This has resulted in higher costs to the Commonwealth of Kentucky, its employers and the citizens of South Central Kentucky. Higher costs create an impediment to patient access. This economic drain "**on the whole for a few**" reduces amounts available for reinvestment in vital services and jobs, which in turn adversely impacts the lives of our citizens.

The now tired and often used argument in defense of CONs "how are we going to survive without these restrictions to fair trade" is easily disputed by looking to the many non CON states that have thriving health services.

It is time to recognize the now detrimental effects of the CONs barriers to lower costs and patient access. We believe this amendment is a positive first step.

Once again, on behalf of the nearly 140 physicians and nurse practitioners at Graves-Gilbert Clinic, and the over 300,000 patient visits we provided in 2014, we are writing to express our **absolute support for the administrative regulation amendment to 900 KAR 5:020.**

Respectfully,

Donald Rauh, M.D.
Board of Directors, Graves-Gilbert Clinic

Main Clinic: 201 Park Street • P.O. Box 90007 • Bowling Green, KY 42102-9007
Medical Arts Building: 350 Park Street • Bowling Green, KY 42101
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LIFEPOINT HEALTH

June 24, 2015

Tricia Orme
Office of Legal Service
275 E. Main St. 5 W-B
Frankfort, KY 40601

Re: 900 KAR 5:020
2015-2017 State Health Plan

Dear Ms. Orme:

I am writing on behalf of LifePoint Health (formerly LifePoint Hospitals, Inc.) and its affiliated companies to express our comments on the proposed changes in the 2015-2017 Kentucky State Health Plan. LifePoint is one of the largest healthcare providers in Kentucky, focusing largely on rural areas. Through wholly owned entities we operate eight hospitals in Kentucky, including: Lake Cumberland Regional Hospital, a 275-bed hospital in Somerset; Jackson Purchase Medical Center, a 107-bed hospital in Mayfield; Meadowview Regional Medical Center, a 100-bed hospital in Maysville; Logan Memorial Hospital, a 75-bed hospital in Russellville; Spring View Hospital, a 75-bed hospital in Lebanon; Georgetown Community Hospital, a 75-bed hospital in Georgetown; Clark Regional Medical Center, a 75-bed hospital in Winchester; Bourbon Community Hospital, a 58-bed hospital in Paris; Clark Regional; and Bluegrass Community Hospital, a 15-bed critical access hospital in Versailles. We also operate numerous outpatient facilities throughout Kentucky. We have more than 32,000 employees in Kentucky.

LifePoint has long supported Kentucky's Certificate of Need program and worked with the Cabinet and its predecessors in the health planning process. We are very concerned that some of the proposed changes will reduce quality of care, harm existing providers, especially rural hospitals, and lead to an unnecessary proliferation of unneeded health facilities and services. Two that are of the most concern to us as an operator of rural hospitals, are the proposal to create broad exceptions to the legislative mandated need methodology for ambulatory surgical centers and the proposal to remove MRI from the State Health Plan.

AMBULATORY SURGICAL CENTERS

We oppose the Cabinet's proposed Ambulatory Surgical Center Review Criteria 5 and 6 at page 60 of the 2015-2017 Kentucky State Health Plan. These criteria create two potentially very broad exceptions to the legislative mandated need methodology for ASCs. This could easily

lead to a proliferation of unneeded ASCs and could lower the quality and raise the cost of outpatient surgery services.

Proposed ASC Criterion 5 would make applications by certain hospitals, or entities with >50% ownership by those hospitals, automatically consistent with the SHP. It does not limit the number or location of ASCs to be established. It does not take into account any factors concerning the need for another ASC in the area. On its face, it appears that it would even apply to out-of-state hospitals proposing ASCs in Kentucky.

We have seen no evidence that the Cabinet has done any analysis as to whether additional ASCs are needed in any particular part of the state and, if so, how many are needed. In the absence of such an analysis, and a methodology adopted from that analysis, this provision not only violates the express language of Part I(A)6) of the State/Executive Branch Budget, but it is also very poor health planning.

Proposed ASC Criterion 6 would make applications by certain physicians or groups automatically consistent with the SHP. Again, this does not appear to be based upon any analysis as to where or how many additional ASCs may be needed. If the Cabinet strictly enforces the requirement that any ASC approved under this provision be limited to procedures already performed by these physicians in their office, the main effect of this language will be to increase the amount that Medicaid and Medicare must pay for these procedures. If that restriction is not strictly enforced, the effect will also be to shift procedures from existing licensed providers to the newly established ASCs. This could have a very negative impact on existing, especially rural hospitals. This is a tremendous threat since the new ASC applications would be exempt from the need methodology required in the State Health Plan.

There is an abundance of hospitals and ASCs in most parts of Kentucky. If there were a need for additional ASCs in particular locations, the Cabinet should, indeed it must, adopt a reasonable need methodology addressing those needs rather than the proposed, broad exceptions which completely swallow the general rule.

According to the most recently published report, the *2013 Kentucky Annual Hospital Utilization and Services Report*, there were 92 hospitals providing surgery services, with a total of 737 operating rooms. According to the Cabinet's May, 2015, *Inventory of Health Facilities and Services*, there were also 44 ASCs in Kentucky, with a total of 152 ORs. There are already existing ASCs in every Area Development District in which LifePoint operates a hospital.

Not only would proposed ASC Criteria 5 and 6 lead to a proliferation of unneeded ASCs, it would also increase the challenges to many hospitals, including rural hospitals. Without a need

methodology or any limit on the number or location of new ASCs, there would be a substantial risk that ASCs could be established in locations that will harm or even jeopardize the existence of some hospitals. It is well documented that many Kentucky hospitals are at risk of failing. Being burdened with the high cost of 24-hour services, indigent care, governmental programs paying less than cost, and other serious threats to their solvency, hospitals cannot afford to have more ASCs syphoning off some of the last remaining profitable services.

For all of these reasons, LifePoint and its hospitals request that the Cabinet delete proposed ASC Review Criteria 5 and 6.

MRI SERVICES

We also oppose the Cabinet's proposal to remove MRI criteria from the 2015-2017 Kentucky State Health Plan. This opposition is based upon quality concerns as well as the threat to existing providers, especially rural hospitals. Because of the statutory CON exemption in KRS 216B.020(1) for diagnostic centers that do not provide SHP covered services, removing MRI from the Plan would effectively remove any CON requirement for MRI facilities.

MRI, like surgery, is one of the few remaining service in which hospitals can make a surplus to help cover other operating losses. The Cabinet's proposal would constitute another opportunity for others to skim some of the last remaining "cream" off the top and greatly jeopardize struggling hospitals. Anyone could establish a free-standing diagnostic center with MRI next door to any hospital, without having to demonstrate need or the ability to provide a quality service.

The MRI criteria in the State Health Plan have not precluded approval of needed MRI services. However, they do make applicants demonstrate a need and ensure a minimum quality. In the last five years, there have been a number of applications for new MRI services that were approved. However, there have been three that were disapproved. Of those, two were disapproved based upon an inconsistency with all the statutory criteria, including need and quality of services.

Indeed, the CON requirement has been useful in preventing poor quality providers from establishing MRI services. The Cabinet should keep MRI in the State Health Plan.

CONCLUSION

Thank you for the opportunity to submit these written comments. As always, we support Kentucky's CON program and will continue to work with the Cabinet in the health planning process.

Sincerely,

Dave Anderson, CEO
Jackson Purchase Medical Center

Tim Bess, CEO
Lake Cumberland Regional Hospital

James Bills, CEO
Logan Memorial Hospital

Tommy Haggard, CEO
Bluegrass Community Hospital

William Haugh, CEO
Georgetown Community Hospital

Joseph Koch, CEO
Bourbon Community Hospital

Robert Parker, CEO
Meadowview Regional Medical Center

Cherie Sibley, CEO
Clark Regional Medical Center

Tim Trottier, CEO
Spring View Hospital

OUR LADY OF BELLEFONTE HOSPITAL
Bon Secours Kentucky Health System

June 29, 2015

VIA U.S. MAIL & FACSIMILE
Tricia Orme
Office of Legal Services
275 East Main Street, 5 W-B
Frankfort, KY 40601
Fax: 502-564-7573

RE: Proposed State Health Plan Changes by the Kentucky Cabinet for Health and Family Services - May 14, 2015

Dear Ms. Orme:

On behalf of Our Lady of Bellefonte Hospital (OLBH), I am writing to formally comment on the proposed State Health Plan changes by the Kentucky Cabinet for Health and Family Services on May 14, 2015.

Observation(s)

- Proposed changes to the Ambulatory Surgery Center language will duplicate services (in areas without need) leading to increased healthcare costs, as well as reallocating dollars and placing the burden of charity care on hospitals that have and are currently serving these populations.

- Proposed changes to the Cardiac Catheterization language [by eliminating the Percutaneous Cardiac Intervention (PCI) pilot program] will be taking a step backwards, and again put Kentucky in the minority of states when it comes to providing safe, lifesaving cardiac interventions to our extremely high risk communities/populations. Not only would the elimination of the PCI pilot program be a setback, but it is completely contradictory to the recent direction of the Cabinet of expanding services to at-risk populations.

Request(s)

- OLBH is in full support of the comments submitted by the Kentucky Hospital Association (KHA) on June 24, 2015 (enclosed), and requests that these recommendations be seen as favorable and appropriate changes made to the final rule.

Thank you for your attention. Please do not hesitate to contact me with any questions or requests for additional information.

Respectfully,

Kevin B. Halter, FACHE
Chief Executive Officer

Enclosure

cc: Senator Robin L. Webb, Representative Tonya Pullin

Kentucky Hospital Association

June 24, 2015

Tricia Orme
Office of Legal Services
275 East Main Street 5 WB
Frankfort, Kentucky 40601

Dear Ms. Orme:

The Kentucky Hospital Association, representing all Kentucky hospitals, appreciates the opportunity to submit comments on the proposed changes to the State Health Plan. The KHA and our member hospitals and systems strongly support having a robust Certificate of Need program in our collective desire to assure access to quality health care services and to uphold the statutory intent of the Kentucky CON program – "to insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth."

The following comments and recommendations have been developed with input from the KHA membership and the KHA Certificate of Need Committee along with approval from the KHA Board of Trustees. We look forward to having the opportunity to meet with the Cabinet in person to answer any questions that may arise from the comments.

Sincerely,

Michael T. Rust

Michael T. Rust
President

Kentucky Hospital Association
State Health Plan Comments
June, 2015

KHA Position on the State Health Plan

Although, KHA had the opportunity to participate in the CON Modernization Comment period, the Cabinet did not afford the opportunity with KHA or its membership in advance of publication to react to the Cabinet's specific proposal included in this plan. There has been no explanation as to the reasoning, need warranting these changes or intended outcome of the proposed changes to the SHP. Additionally, we would like to know what modeling or analysis of the potential impact of these proposed changes would have on existing providers and access to care. We believe it is essential for the Cabinet to withdraw this proposal until the Cabinet has met with providers and industry leaders as well as analyzed and modeled the potential outcomes of these proposed changes. KHA and our members have grave concerns that the majority of the proposed changes have not been fully vetted and could result in significant hardship to existing providers in Kentucky and could actually counter the goal to improve access and quality care. Such sweeping changes should not be done quickly and without serious contemplation, input and collaboration with the industry that is effected by the rule.

KHA produced a white paper, "Certificate of Need: Stabilizing Force for Health Care Transformation" and submitted that document to the Cabinet during the CON Modernization comment period. The core principles, which align with the Cabinet's modernization objectives, highlighted in that paper continue to be the guiding tenet for KHA and our member hospitals and health systems. In summary, the white paper outlines the following:

- Principle 1: Supporting the Evolution of Care Delivery – The evolution in health care delivery that is at the heart of Health Care Reform is not frustrated by CON regulation or the existing criteria in the State Health Plan (SHP). The driving force for new models of care is altering payment incentives, which are independent of CON regulations. However, CON is a stabilizing force which allows existing providers to embrace new payment models, like accountable care organizations and payment bundling, which require a level of risk to be taken by providers. CON as proposed by the Cabinet deregulation under current payment conditions would result in greater fragmentation rather than enhancing the integration of care.

- Principle 2: Incentivizing Development of a Full Continuum of Care – The development of a full continuum of care is precisely the objective of new delivery models that are evolving. The creation of such delivery systems does not require major changes to Kentucky's CON regulations or SHP criteria. In most parts of Kentucky today, there is sufficient availability and capacity of health services to allow new models of care to be developed without allowing unchecked proliferation of new services and facilities. The focus of health care transformation centers on improving population health. Primary care and prevention services for the most part are not covered by the CON program in Kentucky.

- Principle 3: Incentivizing Quality – Quality of care will be a function of the care management systems implemented by organizations. CON deregulation would likely have the effect of diminishing quality of care by reducing volumes across all providers and stretching scarce resources over a greater

number of providers. CON standards in the SHP currently support quality as CON criteria seek to ensure that new facilities operate at volumes that are sufficient to provide quality services as well as assuring that new volume does not come at the expense of existing providers where the lowering of their volumes could reduce quality of existing programs.

- Principle 4: Improving Access to Care – CON deregulation could have the effect of reducing access to care by destabilizing local health care systems. Smaller, rural hospitals and safety-net hospitals in particular are vulnerable to the loss of profitable patients to private organizations that would be developed without CON standards in place. Additionally, new providers likely to enter the market if CON is repealed or weakened would probably target serving patients with commercial insurance which would have an adverse impact on improving access for Medicaid or indigent patients.

- Principle 5: Improving Value of Care - There is no evidence that states without CON programs offer higher value care. To the contrary, in most cases, states without CON have significantly greater duplication of resources and operate on average at lower volumes per provider.

- Principle 6: Promoting Adoption of Efficient Technology – There is simply no relationship between the adoption of efficient technology and CON regulation. Administrative and clinical information systems are not subject to specific CON regulations in Kentucky. With the exception of a few high dollar types of equipment, hospitals and other providers are able to acquire new equipment and technology without facing impediments from the CON program.

- Principle 7: Exempting Services for Which CON is No Longer Necessary – There are no services that the Deloitte Report recommended for elimination of CON review that would appropriately be deregulated. The concern with ensuring sufficient capacity in the future to accommodate a growing base of insured Kentuckians is not based on objective analysis. There are no capacity issues or other considerations that would require the elimination or deregulation of CON to ensure adequate availability of care. The impact on rural hospitals and safety-net hospitals must also be considered when exempting services from review, and such changes could challenge the ability of these providers to offer the same level of access in the future. It is premature today to make changes that will result in greater fragmentation rather than integration of providers. The CON program should be continually reviewed, as it has been, and revised in accordance with health planning principles which consider actual changes in the delivery system and data documenting needs and gaps in services.

Supporting Rural Providers

We understand it is the Cabinet's intent to implement changes to the State Health Plan (SHP) which would be advantageous to rural providers aiming to improve access to quality health care services and support services which improve population health. The Cabinet is aware of a recent study released by State Auditor Adam Edelen which illustrates the ongoing challenges many Kentucky rural hospitals face in maintaining access to essential services and achieving a level of profitability. In the last year, two Kentucky hospitals have closed and an additional hospital has filed for bankruptcy. The challenges rural hospitals face are real and they impact the communities and the health of the populations they serve. We are quite disappointed that the proposed changes to the SHP fall short of protecting existing rural

providers from the unnecessary proliferation of costly health care services. To the contrary, the proposed plan would remove the few services – imaging and outpatient surgery – which are profitable and allow the hospital to maintain access to an emergency department and other essential services to their community. The plan also forecloses the opportunity for some rural hospitals to expand access to services by eliminating the angioplasty program and restricting home health.

There is also a missed opportunity to create a pathway for some small rural hospitals to seamlessly convert to appropriately sized and financially feasible outpatient centers which better meet the needs of the populations they serve. Reports nationally and observations within our own state demonstrate the distinct value that rural hospitals provide to both the physical health of their patients but also the economic health of the communities. We implore the Cabinet to review these proposals and ask the question, *how does this proposal support access to care in rural Kentucky.* We believe the proposal has the potential to further exacerbate the problems many small rural hospitals face and if more hospitals close, the result is the displacement of rural Kentuckians from their homes and local support systems to access health care.

Use of Quality Metrics

KHA applauds the Cabinet for proposing new quality criteria within the State Health Plan as a condition of application. This strongly reflects the statutory intent for the Certificate of Need program. Additionally, we concur with the Cabinet that quality data utilized should be consistent with measures that have been vetted by national organizations like the National Quality Forum and the Centers for Medicare and Medicaid Services (CMS). ***KHA believes that measures must be evaluated for both accuracy and appropriately linked or complimentary to the specific services in question within the SHP for it to be included within the criteria.***

KHA, however, opposes the use of the CMS readmission measure and data for determining eligibility of hospitals to apply for services. There have been numerous national reports and studies which have found that the CMS Hospital Readmissions Reduction Program unfairly penalizes hospitals that provide care for communities with poor socioeconomic indicators. Specifically, the readmission measure does not appropriately adjust for the socioeconomic factor which greatly influences post acute outcomes and the ability and likelihood that patients follow their discharge plan, in spite of the hospitals efforts to best manage the patient after they have been discharged. A sample of these reports follow:

- **A 2013 MedPAC Report:** http://www.medpac.gov/documents/reports/jun13_entirereport.pdf The Medicare Payment Advisory is a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program. Their 2013 report highlighted the importance of risk adjustments and recommended the readmission measure should be improved by evaluating hospital readmission rates against a group of peers with a similar share of poor Medicare beneficiaries and to adjust accordingly.
- **Kaiser Health News report:** http://www.kaiserhealthnews.org/Stories/2012/August/13/hospitals-treating-poor-hardest-hit-readmissions-penalties.aspx. Analysis by Kaiser Health News showed that the Readmissions Penalty program penalizes most hospitals that treat larger populations of low-

income patients when these same hospitals need more resources in place to help patients when they leave hospitals.

- **Health Affairs:** http://content.healthaffairs.org/content/33/8/1314.abstract.
  A report by Health Affairs in August 2014 addressed the concern for Safety-Net Hospitals which treat more low-income patients and the unfair penalties for these facilities.

Additionally, legislation has been introduced at the federal level to address these concerns. *Establishing Beneficiary Equity in the Hospital Readmission Program Act* would adjust the Hospital Readmissions Reduction Program to account for certain socioeconomic and health factors that can increase the risk of a patient's readmission, such as being dually eligible under Medicaid and Medicare.

It is important to note, that in our member hospitals and systems' work towards transitioning their healthcare delivery models and improving outcomes and overall health, hospitals must be able to offer services that supports their work to improve long-term outcomes for their patients. The proposal to use the Readmission Measure particularly within the State Health Plan is counter to that effort. Moreover, post acute services, like home health, may be one of the more valuable tools for hospitals serving comparingly low economic populations to effect improvement on long term outcomes.

We would like to reiterate that reducing readmissions is currently the highest quality improvement focus of our hospitals collectively, according to a recent survey we conducted of our members. They have participated in a great deal of education and training around best practices for discharge planning and working with community partners and physicians. Reducing preventable readmissions is a shared goal for all in healthcare. All Kentucky acute care hospitals are involved in benchmarking readmission data and implementing strategies and resources to actively reduce the readmission rate. KHA welcomes the opportunity to discuss these strategies and activities further. However, our membership is opposed to incorporating a known flawed readmission measure within the SHP and we request it be deleted from the revised criteria as it would unfairly penalize these hospitals serving a disproportionate share of poor patients from being able to expand access to services.

In addition, KHA would like to point out that critical access hospitals are not included in the readmissions and mortality reporting requirement and therefore there is no data available for these facilities. Is it the Cabinet's intent to exclude these hospitals from the opportunity to expand services like Home Health which could benefit their community and long-term outcomes of patients? As the plan is written, "hospital" is not clearly defined in several section including the Home Health and Ambulatory Surgery Center. It is so loosely described that it could allow out-of-state hospitals from providing a broad range of services in this state.

Technical Notes and Common Review Criteria

KHA appreciates the Cabinet's efforts to improve upon the Technical Notes section of the SHP by ensuring the language is consistent with current CON regulation and to incorporate technical language within the specific criteria for services covered in the SHP.

KHA opposes the requirement within the Common Review Criteria for applicants to have a signed agreement with the Kentucky Health Information Exchange (KHIE) and to be both submitting and accessing data through KHIE. While acute care hospitals and some other providers have made significant strides in implementing electronic medical records (EMR), many providers have not had the same opportunities and resources to support adoption of EMRs. Specifically, federal meaningful use funding was not available for rehabilitation and psychiatric hospitals and therefore, many of these hospitals have not had the resources to adopt EMRs at the same pace as their acute care hospital counterparts. There are other non-hospital providers of services covered under the SHP that have similar challenges. KHA believes that providers intending to expand or build a service should not be unjustly prohibited from doing so because of lack of resources available to implement systems that are extremely costly to both implement and maintain. **While KHA supports the Cabinet's desire to facilitate and encourage the growth of EMRs and other valuable technology, we feel strongly that these criteria are inappropriately applied to the SHP. We ask the Cabinet to strike #2 and #3 of the Common Review Criteria.**

Comprehensive Physical Rehabilitation Beds

KHA supports allowing existing providers with Physical Rehabilitation beds the opportunity to expand their bed component if they meet utilization thresholds and quality criteria. The ability to expand services by existing providers if target occupancy has been maintained is consistent with other areas of the Plan, including the Acute Bed Need criteria. We also support use of quality metrics as a requirement for applicants to be eligible to apply. However, we have noted a problem with the proposal as it relates to quality indicators for Inpatient Rehabilitation Facilities (IRF). The CMS IRF Quality Reporting Program has been underway for several years, however, the pressure ulcer data and the catheter associated urinary tract infection (CAUTI) rate data is not yet available publicly (through a CMS Compare web site) in order for a national average to be utilized. The CMS Inpatient IRF Proposed Rule indicates that CMS plans to release this data publicly in the Fall of 2016. If the Cabinet does not want to delay the implementation of this change to the SHP and the ability of hospitals to apply for additional beds then KHA recommends the Cabinet consider allowing applicants to submit their Pressure Ulcer and CAUTI rates to the Cabinet and that those rates be compared to the published Pressure Ulcer and CAUTI national rates for acute care hospitals in the interim.

Additionally, we urge the Cabinet to change the requirement for acute care hospitals wishing to expand their bed capacity for existing inpatient rehabilitation beds be held to the same quality metrics as the free-standing inpatient rehabilitation facilities – Pressure Ulcer and CAUTI. Furthermore, applicants should be required to meet or exceed national benchmarks but should *not* be required to exceed the benchmark.

Special Care Neonatal Beds

KHA recognizes the Cabinet's effort to correct the criteria and to remove the requirement for existing providers of Level IV to have a written affiliation agreement with another Level IV facility when applying

for Level II or III beds. KHA would like to recommend a slight change in the criteria for Level III beds regarding the on-site availability of a neonatologist. The proposal includes a 15 minute requirement for on-site availability. KHA recommends this criterion be changed from 15 minutes to 30 minutes which is consistent with federal EMTALA regulations, other CMS Conditions of Participation and is also consistent with most hospital medical staff bylaws.

Long Term Care

We applaud the Cabinet for recognizing the ongoing challenge with the availability of nursing facility beds in the state and we want to particularly emphasize the challenge related to placing medically complex patients in appropriate long-term care settings. KHA supports the principle of proposed changes to the criteria to allow for the transfer of beds from one provider to another provider if quality and occupancy criteria are met. We want to emphasize that quality metrics should be reasonable so that there is appropriate opportunity for the movement of beds. There is also concern that the occupancy rate requirement coupled with the quality performance requirement could limit the ability for this transfer to take place. However, this proposed change effects only minor improvement on the continued patient placement challenges hospitals are facing. KHA has established a work group to analyze the severity of this problem and we are learning from a range of hospitals that when patients cannot be placed appropriately, hospitals must continue to care for the patient in the inpatient setting but without any payment from insurance or MCOs until a long term care facility will accept the patient. Hospitals are losing substantial money in these situations. Often patients must be placed out of state, away from family and support resources, where there is better bed availability. KHA would like the opportunity to work with the Cabinet to discuss how we can develop a system to more appropriately care for Kentuckians close to their families and support systems.

Hospitals have identified a solution to the capacity issue. Some hospitals in the state are experiencing a reduction in inpatient utilization and have beds no longer in operation. We request the Cabinet include an allowance for hospitals to convert underutilized acute care beds to nursing facility or long term care beds. KHA suggests the following language be added to the Long Term Care criteria:

> *An application to convert underutilized acute care beds to long term care beds shall be consistent with the Plan if the following conditions are met*
>
> 1. *The applicant is an acute care hospital and the occupancy of acute care beds in the facility is less than 70% according to the most recently published Hospital Utilization and Services Report, and*
> 2. *All of the proposed long term beds are being converted from licensed acute care beds, and*
> 3. *All of the long term care beds will be implemented on site at the applicant's existing licensed facility*

KHA recommends an addition to the exception under proposed section #5 to limit the transfer of beds within a planning area of the county and contiguous counties. Allowing minor exceptions to strict need criteria is an important strategy to best meet the needs of the citizens of the Commonwealth and to

improve the ability of providers to serve their populations appropriately. However, KHA strongly supports maintaining criteria, even within exceptions, to ensure that services are granted based on population and planning area based needs. Allowing services to move from one area of the state to potentially any other area within the state would depart from that overarching goal and planning strategy and could set a poor precedent for other areas of the plan.

Home Health Agency

KHA commends the Cabinet for recognizing the need for criteria to allow existing providers, especially hospitals, to provide and expand home health services to meet the long-term needs of patients. Hospitals are increasingly accountable for ensuring that patients receive effective and efficient care throughout the continuum of care. Examples of this are the CMS Readmissions Reduction Program and the Value Based Purchasing Program. Because acute care hospitals' reimbursement rate is impacted by how effective post-acute services are at preventing readmissions to hospitals, hospitals should have the opportunity to provide home health services. No other provider has a greater responsibility in ensuring that home health services are effective in improving the health of patients in an effort to prevent the need for a higher acuity patient stay either in a hospital or nursing home.

We understand the desire of the Cabinet to incorporate quality criteria within the Home Health criteria. However, we believe the criteria proposed for hospitals do not appropriately align with this particular service and should be deleted. We are particularly concerned with the use of the readmission measure for reasons already outlined. Home health services may be one of the most valuable tools for hospitals to implement in their ongoing work to effect improvement in hospital readmissions and mortality. Furthermore, hospitals with good readmission rates may actually indicate the hospital has an effective home health agency partnership established while hospitals with higher readmission rates may not have the same availability of effective services. We urge the Cabinet to delete the readmission measure from the Home Health criteria because it is flawed and will penalize the very hospitals that need home health to improve their readmission rates.

The Cabinet in two sections, Home Health and Rehabilitation Beds, has proposed a requirement for existing providers to meet national benchmarks for all 12 measures within the readmissions and mortality measure sets and additionally *to exceed the benchmark* for at least one of these measures. It is important to note that this additional factor is extremely limiting and prohibitive. Only six acute care hospitals meet this requirement according to the most recently available Hospital Compare Data. We oppose this additional requirement for any quality metric. Meeting the national benchmark should be adequate.

KHA does oppose proposed criterion #6 which would create a need criteria exemption for Accountable Care Organizations. While we understand the intent of the Cabinet is to support the health care model transformation and to enable ACOs to provide the full continuum of care in an effort to best manage the patient and outcomes, not all providers operating as an ACO have the knowledge, resources or expertise to provide Home Health Services.

Cardiac Catheterization

KHA opposes the removal of the cardiac catheterization without surgical back-up pilot project from the criteria within the SHP. It is estimated that approximately 25% to 35% of the catheterization laboratories in the United States operate without open heart surgery back-up[1]. According to the American College of Cardiology (ACC) 2012 Consensus document, "the remarkably low risk now associated with diagnostic cardiac catheterization suggests that only a few cardiovascular patients cannot safely undergo procedures in these laboratories" and that the number of laboratories performing coronary interventions without surgical back-up has safely increased in recent years. Furthermore, there are only a few exceptions which include patients with complex congenital heart disease and pediatric patients, which should be treated only in full-service facilities.

As the ACC indicates, programs providing interventional cardiology without open heart back-up have been growing nationwide safely in recent years. Kentucky implemented the current pilot program following a very thoughtful and scientifically based pilot approach based on appropriate selection criteria and evaluation of outcomes. The program has received strong support and approval from tertiary facilities affiliated with the programs as well as from Dr. Layman Gray who evaluated the initial pilot project on behalf of the Cabinet to help determine safety and efficacy.

Included in the existing pilot process, through 900 KAR 6:120, are numerous quality assurance mechanisms to ensure a pilot hospital is performing at high quality standards and that outcomes are safe and effective. The regulation also provides the Cabinet's Office of Health Policy numerous opportunities to intervene if there are any concerns related to quality:

- Reporting of death and adverse events by hospitals within established timeframes
- Joint Performance Improvement Committee with collaborating tertiary hospital that includes a requirement for the development and implementation of a plan of correction if problems are identified.
- Review of the pilot hospital performance by an outside evaluator including a university affiliate
- The ability of the Cabinet to terminate a trial if outcomes warrant termination.

There is ample opportunity within the existing SHP criteria and 900 KAR 6:120, the licensure regulation on pilot hospitals, to closely monitor pilot hospitals providing cardiac intervention services to ensure an appropriate level of quality and to intervene when reporting and outcomes indicate a hospital is not meeting established standards.

This pilot program was established to provide improved access and life saving treatment to Kentuckians – 45% of which live in rural areas – suffering from acute myocardial infarction. Kentucky looked to other states, more advanced in expanding this service outside of surgical back-up including Massachusetts, and to published guidelines from the ACC – when creating this pilot. The consensus in the industry is

[1] 2012 American College of Cardiology Foundation/ Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

that it is safe to practice interventional cardiology without open heart surgery back-up if ACC guidelines are practiced closely and there is a level of quality assurance monitoring. The existing program within the SHP aligns with this recommendation.

There are a number of hospitals in the state which have been working to build their diagnostic programs into interventional programs. These facilities have invested significantly in technology, education, staffing and other resources in the effort to best meet the health care needs of their community. At a time when most every state has moved or is in the process of moving to allow this, it does not make sense that Kentucky proposes changes to the SHP which would move us backwards, away from the most effective and innovative model of care for patients with life-threatening conditions.

KHA strongly encourages the Cabinet to withdraw the proposal to eliminate the pilot angioplasty program from the SHP criteria. We welcome the opportunity to work with the Cabinet to review the existing collaborative relationship requirements, review standards and reporting processes to determine if there is a need for improvement upon existing procedures. The value of pilot programs is the ability to improve upon processes and ultimately outcomes.

<u>Magnetic Resonance Imaging Equipment</u>

KHA opposes the proposal to eliminate need criteria for establishing Magnetic Resonance Imaging Equipment or MRI. KHA understands that MRI is a widely available and utilized service in many health care settings. Since 2009 there has been approximately 17 approved out of 20 MRI applications. This is an indication that the MRI criteria within the SHP is being appropriately applied and that all applications which are reasonable are accepted.

However, there are ongoing concerns about quality of services, particularly the quality of the magnet in equipment. The primary concern of the members is in regards to the lack of quality equipment in some outpatient settings. The potential for this to become a growing problem in Kentucky if MRI is removed from the formal review process has been observed in facilities in border state communities. Many members have observed that MRI centers established outside of CON programs in bordering states have low quality scanners. When Kentucky-based physicians try to read the results from these MRI procedures for patients who have gone to low cost/low quality centers, the quality of the scan does not allow the physician to act or treat on quality and reliable information. This often results in the need for a repeat scan by a higher quality machine. Therefore, the result is duplication of health care services to ensure the appropriate level of quality and ultimately an increase to health care costs. The SHP criteria at the very least establishes a requirement for applicants to ensure there is a need for the equipment and that equipment will meet a minimum level of quality. We urge the Cabinet to maintain MRI under the formal review process. The formal review process also assures the quality in the interpretation of the scans because applicants must specify the credentials of the physicians. We offer the opportunity to discuss with the Cabinet the opportunity to promote a standard level of quality for equipment through licensure.

Even accrediting organizations, like the American College of Radiology (ACR) recognize specific levels of quality for both magnets and for physicians interpreting the results. The Cabinet should look to these organizations and ensure any changes would be in keeping with the appropriate level of quality established by such organizations.

An alternative approach to allowing MRI to expand would be to have an exception to criteria which requires accreditation from the American College of Radiology (ACR) by applicants. One accreditation requirement is that a minimum magnet quality be in place.

Megavolt Radiation Equipment

We appreciate the Cabinet addressing the ongoing problem both the Cabinet and providers face with CON approved but not licensed health services. The proposed changes to address this consists of a change to the Megavoltage Radiation Therapy Program definition to include *only licensed centers and CON approved but not licensed within the previous three years*. While we support this effort to ensure that applicants are not penalized by programs which have been approved but not implemented, we believe there is a more appropriate way to address this ongoing problem. We encourage and support the Cabinet in actively monitoring Progress Reports and we believe that the Cabinet should revoke applications for programs which do not demonstrate progress toward full implementation within an appropriate timeframe. KHA believes that the proposed definition language could set an unwanted and unnecessary precedent for other services and could adversely impact other applicants for large-scale projects which are making steady progress. We encourage the Cabinet to remove this definition and to address the ongoing issues by vigorously reviewing CON Progress Reports and revoking Megavolt Radiation Equipment CONs for applicants which have not made progress in three years or more.

KHA does not support the exception to the need criteria within proposed criterion #3. We firmly believe there should be need-based criteria for Megavoltage Radiation Equipment. Additionally, the proposal would seemingly allow an out-of-state hospital to establish this equipment anywhere in the Commonwealth. Because radiation treatment is a costly and highly technical service, Kentucky should aim to ensure applicants are Kentucky-based providers and that applicants should be held to population based need criteria within the defined planning area because it will decrease volume at existing providers which will increase overall cost of care.

Ambulatory Surgery Center

KHA strongly opposes exceptions to population based need criteria to establish an Ambulatory Surgery Center (ASC). We would like to reference the 2014 KHA study "CON: Stabilizing Force for Healthcare Transformation" which was submitted to the Cabinet for consideration in December 2014 during the open comment period on CON Modernization.

> *"[The] Kentucky General Assembly has twice weighed in on the issue of ASCs. Legislation was passed in 2012 clarifying legislative intent by specifically mandating that ASCs be required to obtain a CON. Then, in the 2014 legislative session, the Kentucky General*

Assembly took action to assure that CON review for ASCs would be conducted under the formal review process by requiring that the State Health Plan contain specific review criteria that is based on population need. In taking these actions, the General Assembly recognized the importance of CON in assuring quality and access as it relates to outpatient surgery.

Recommendations for altering or loosening the ASC criteria are based on unreliable information. Data published by the Cabinet annually in the Utilization and Services Report indicate there is ample capacity within existing ASC and hospital outpatient departments to provide services throughout the state. The data published in the Deloitte Healthcare Facility Capacity Report regarding ASCs is neither reliable nor replicable and therefore should not be used to guide any policy changes.

KHA conducted a survey in October 2014 of hospital outpatient surgery departments and ambulatory surgery centers. We learned there are a number of available surgical suites not in use primarily because there is a lack of demand for procedures and secondarily due to surgeon availability. Data indicate there is even greater capacity available to meet need in the immediate future. Additionally, 85% of responders indicated they have the ability to flex their hours of operation to meet patient demands if and when those change. Forty-four percent (44%) of responders report they flex hours to meet needs on a regular or weekly basis. Finally, 89% of responders indicated their scheduling lead time was two weeks or less, a clear indication there are not long waits for outpatient surgical procedures. Only 2% indicated a wait time of greater than one month. And responders indicated the primary driver of wait time or "lead time" is physician preference or availability.

When we evaluate outcomes in other states where CON was revoked or ASC criteria was eliminated, we have learned that there is gross proliferation of ASCs, there are documented incidences of cherry-picking by profit-seeking providers and investors and there are adverse impacts to community and safety-net hospitals which are left to provide care for only the sickest patients and those with poor insurance reimbursement. A recent study published by State Auditor Adam Edelen illustrated the ongoing financial challenges many rural Kentucky hospitals continue to encounter. Allowing ASCs to be established by any hospital (including out-of-state) virtually anywhere in the Commonwealth will have detrimental impacts to the existing hospital providers fighting to provide a full range of services to all patients regardless of their ability to pay.

If the goal of the Certificate of Need program is to ensure there is access to quality health care services, to contain health care costs and to prevent the unnecessary duplication of services, then the recommendations to provide criteria exemptions to the ASC criteria within the SHP are in direct conflict with the intent of the CON program. The existence of ample capacity within ASCs and outpatient departments of hospital surgical programs as published by the Cabinet indicates there is no significant need for additional outpatient surgical capacity. Criterion #5 offers an exemption for applicants with a majority hospital (even a non-Kentucky hospital as written) ownership to establish and ASC anywhere within the state if quality metrics are met. There are a number of problems with this recommendation:

- This would allow non Kentucky hospitals to establish an ASC in Kentucky
- This would promote cherry-picking
- There is no reference or requirement to establish the ASC within the established planning area – the county and contiguous counties. As discussed previously, the SHP should maintain the use of planning areas in keeping with the intent of the CON program to provide community level planning and access to care.
- The quality metrics included in the requirement, readmissions rate and mortality rate, are related to mostly non-surgical *inpatient* care and are not a good measure of quality related to outpatient services.

The proposal under criterion #6 would allow the private office of a physician or physician group which is 100% owned by those physicians to apply to establish an ASC if they have been operating for ten years and they are proposing to do surgical procedures which they have performed for the previous five years in their office. There are numerous problems with this proposal as well. If the physician(s) has an established office where it has already been performing the procedures it is proposing to perform in an ASC in its office for five years then the proposed change does nothing to address an identified need, improve quality or contain costs. In fact, it would increase costs to health care because it would merely increase the reimbursement to the physician by adding a facility fee to the payment for procedures already being performed on existing patients. The proposal does not adequately address quality risks associated with performing surgical procedures in a physician office. What would prevent a physician with an established ASC from expanding the procedures performed in the ASC outside those performed in their office in the last 5 years? Additionally, there are numerous reports nationally, including some high-profile reporting, of procedures with bad outcomes in ASCs. The leading factor to these adverse outcomes and sometimes death is often use of anesthesia without proper training, experience and/or monitoring.

KHA strongly supports maintaining the ASC criteria as is written in the current plan, including maintaining language to require ASCs to have transfer agreements in place with receiving hospitals within 20 minutes of the ASC. Existing language in the state budget requires a population based need criteria to be used in the *review* of CON applications for ASCs. The proposed changes are in direct conflict with that language as they provide a mechanism for review for ASC approval nothwithstanding the need criteria. Finally, we oppose the changes based on use of inappropriate quality metrics and potential for establishment of ASCs by out-of-state providers virtually anywhere within the Commonwealth of Kentucky, even in counties where an ASC is already operating.

Chemical Dependency

KHA opposes the Cabinet's proposal to remove Chemical Dependency beds from the SHP and the formal review process. The KHA Psychiatric and Chemical Dependency Hospital Forum (Psych and CD Forum) represent providers of both free standing hospitals and acute care hospital-based psychiatric and chemical dependency units. Members of the Forum have been meeting regularly to discuss the changing policy around expansion of care for patients suffering from chemical dependency. The KHA and our members are glad to continue to work with the Cabinet to revise the existing criteria for chemical

dependency need criteria to be in keeping with current practice trends and best practices but we feel strongly that chemical dependency beds must remain under the formal review process.

Historically, there is consensus among KHA members that we may benefit from improving the SHP criteria to better reflect current utilization and practice models. It should be noted that current models for treating patients with chemical dependency diagnoses include an extensive continuum of care. Specifically, there are a full range of services, within multiple provider settings, that must be included when we consider and plan for our current and future chemical dependency treatment needs. Within these services are medical detoxification, inpatient treatment, partial hospitalization programs, intensive outpatient programs, residential treatment facilities and other levels of care that are included in the best practice models.

We understand that the impetus for the Cabinet's proposal to remove the Chemical Dependency Bed need criteria from formal review was legislation recently passed by the General Assembly – SB 192. The legislation created a CON exemption for the establishment of *free-standing residential substance use disorder treatment programs* limited to 16 beds. These residential facilities, for which there is no licensure regulation at this time, should not be confused with inpatient chemical dependency treatment.

The Inpatient hospital chemical dependency beds are considered to be an acute inpatient level of care – not residential care – which are used to provide medical detoxification for drug and alcohol dependency and have a short length of stay. While the type of facility that is outlined in SB 192 is not yet defined in Kentucky regulation, residential facilities in general are very different from inpatient chemical dependency beds, which follow a medical model. Residential facilities typically provide 28 day counseling programs, often not providing medical oversight and supervised detoxification. It is imperative to keep the chemical dependency treatment beds in CON because these are acute hospital beds and complete deregulation would have a detrimental impact on existing providers by potentially reducing volume and allowing for cherry-picking of the most well-insured patients.

Outpatient Health Center

KHA is opposed to the Cabinet's proposal to remove Outpatient Health Care Center from the SHP and the formal review process. We understand that the category and supporting criteria are currently specific to only one community which already has established the facility. However, we are concerned that removing this component from the SHP would allow these centers to potentially be established anywhere in the state by anyone with only minor changes to the existing licensure regulation. The existing licensure regulation allows an outpatient health center to provide 24 hour emergency services, primary care, radiology, MRI, and ambulatory surgery – essentially a hospital without beds. Although the current licensure regulation restricts the center to a county with a population of 60,000, removal of that provision would allow these centers to be built anywhere. These centers could function as an outpatient hospital without meeting hospital requirements such as EMTALA and therefore could threaten the existence of Kentucky's rural hospitals. Furthermore, ASC and MRI are separately covered in the SHP under distinct review criteria. Under the Boone Spring decision, no service can be covered

under non-substantive review for which there is a component under the SHP. Because ASCs and MRIs are under formal review, the Outpatient Health Care Center cannot be reviewed under non-substantive review.

As previously discussed with the Cabinet, KHA and our members do support the ability of existing hospital providers with declining inpatient volume threatening their long-term financial integrity to have a mechanism to *seamlessly* convert, without having to close completely, into an Outpatient Health Center. This would allow for the continued access to primary care, emergency services and ambulatory surgical services within the community. There are a number of federal demonstration projects for similar models being conducted by the Centers for Medicare and Medicaid Services. Additionally, there have been at least two bills introduced in Congress to offer alternative care delivery models for small and rural hospitals. We believe as we continue the transformation of the healthcare delivery model in future months and years, there may be Kentucky hospitals that could benefit from a model of this nature. Therefore, KHA supports retaining the Outpatient Healthcare Center component in this SHP and revising it to apply to the conversion of existing acute care and critical access hospitals to a center located in the same county as the hospital.